IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* JEFF LANDRY, in his official capacity as the Attorney General of the State of Louisiana, *Defendant*.	Case No. 23-1042 JUDGE: MAGISTRATE JUDGE:

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. The Constitution's Supremacy Clause makes federal law "the supreme Law of the Land" and prohibits States from enacting legislation that interferes with federal policies and prerogatives. U.S. Const. art. VI, cl. 2. This case challenges a recently enacted Louisiana statute that would undermine the supremacy of federal law by inserting Louisiana officials into the management of a federally created, federally administered prescription drug program. The state statute seeks to dramatically expand the scope of the federal program; to impose massive new financial obligations on program participants; to create state-law procedures and penalties for compelling compliance; and to empower the Louisiana Attorney General to police and punish violations—all based on a reading of federal law which the federal courts have *already* rejected, and which the courts have forbidden federal officials from enforcing. Louisiana's statute thus violates the Supremacy Clause: When binding precedent forbids federal officials from enforcing

an erroneous interpretation of federal law, state officials may not seek to enforce that same interpretation under state law.

2. The federal 340B Drug Pricing Program, 42 U.S.C. § 256b (Section 340B), caps the prices that drug manufacturers can charge for out-patient medications sold to certain healthcare facilities, called "covered entities," that cater to underserved populations. Congress carefully crafted this federal scheme and limited participation in the program to fifteen specific types of covered entities. Off-site, for-profit pharmacy chains (like CVS or Walgreens) conspicuously were *not* included on the list of covered entities.

3. The Health Resources and Services Administration (HRSA), a subagency of the Department of Health and Human Services (HHS), oversees the program. For the first two decades of the 340B program's existence, HRSA advised that each covered entity could engage a single external "contract pharmacy" to distribute the covered entity's discounted drugs. In 2010, however, HRSA issued new guidance purporting to allow covered entities to enter into contracts with an *unlimited* number of off-site, for-profit pharmacies. Over the ensuing decade, use of 340B "contract pharmacies" ballooned to more than 100,000 documented arrangements. What is more, the five largest national pharmacy chains (CVS, Walgreens, Walmart, Rite-Aid, and Kroger) accounted for a combined 60% of all contract pharmacies, siphoning off financial benefits intended for needy patients.

4. In response to these systemic abuses, some drug manufacturers, including AstraZeneca Pharmaceuticals LP (AstraZeneca), adopted policies limiting the number of contract pharmacy arrangements they will recognize. Beginning October 1, 2020, AstraZeneca implemented a policy recognizing one contract pharmacy for each covered entity lacking its own in-house pharmacy.

5. Multiple federal court decisions confirm that AstraZeneca's policy complies fully with the 340B statute.

6. In a decision earlier this year, the U.S. Court of Appeals for the Third Circuit found that AstraZeneca's "restrictions on delivery to contract pharmacies do not violate Section 340B." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 706 (3d Cir. 2023). The Third Circuit therefore "enjoin[ed] HHS from enforcing against" AstraZeneca HHS's "reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies." *Id.*

7. On May 5, 2023, the United States District Court for the District of Delaware on remand entered a permanent injunction—to which the government stipulated—enjoining HHS, HRSA, and their officials from "enforcing against AstraZeneca the agency's reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies." Final Judgment at 1, *AstraZeneca v. Becerra*, No. 1:21-cv-27 (D. Del. May 5, 2023), ECF No. 123 (Exhibit 1).

8. One month later, on June 12, 2023, the State of Louisiana enacted a statute seeking to achieve under state law precisely the same result that federal courts had already rejected. The Defending Affordable Prescription Drug Costs Act, known as Act 358, requires pharmaceutical manufacturers to offer 340B-discounted pricing to an unlimited number of contract pharmacies, thus purporting to outlaw contract pharmacy policies like AstraZeneca's. The statute, which took effect August 1, 2023, is unlawful and should be enjoined for several reasons.

9. *First*, Act 358 creates a direct conflict with—and thus is preempted by—federal law under the Supremacy Clause of the U.S. Constitution, U.S. Const. art. VI, cl. 2. Under the Supremacy Clause, "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Aldridge v. Miss. Dep't of Corr.*, 990 F.3d

868, 874 (5th Cir. 2021) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1988)). Act 358 directly conflicts with the Third Circuit's ruling and the Delaware Federal Court's injunction, which make clear that the federal 340B statute does *not* obligate manufacturers to deliver discounted drugs to unlimited contract pharmacies and forbid officials from trying to impose that obligation on AstraZeneca. State officials may not impose it either.

10. *Second*, Act 358 "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (citation omitted). By empowering state officials to enforce obligations purportedly imposed by the federal 340B statute, Act 358 frustrates Congress's objectives and interferes with the enforcement regime that Congress created for resolving disputes under the 340B program, which Congress intended to be comprehensive and exclusive. States cannot establish parallel enforcement regimes for federal programs—giving state officials power to impose additional obligations and punish violations, and thereby encroaching on the federal government's authority to set and define federal enforcement priorities.

11. *Third*, Act 358 is preempted because Congress both created and occupied the entire field of 340B regulation. The 340B program is an exclusively federal scheme that is designed to be "harmoniously" administered on a "nationwide basis," with federal officials "hold[ing] the control rein." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 120 (2011). Act 358 impermissibly intrudes into this uniquely federal domain.

12. *Fourth*, Act 358 also violates the Contracts Clause of the U.S. Constitution. *See* U.S. Const. art. I, § 10, cl. 1. The 340B program is enforced through agreements between the HHS Secretary and manufacturers. 42 U.S.C. § 256b(a)(1). Act 358 substantially interferes with the operation of those agreements and with manufacturers' rights and obligations thereunder.

13. AstraZeneca therefore seeks an order: (1) declaring that Act 358 is preempted by federal law; (2) declaring that Act 358 is unconstitutional as applied to AstraZeneca under the Contracts Clause; and (3) enjoining Defendant Jeff Landry, the Attorney General of Louisiana, from enforcing Act 358 against AstraZeneca through investigative demands, lawsuits seeking civil penalties or other relief, or in any other manner.

JURISDICTION AND VENUE

14. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the Constitution of the United States). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02.

15. This Court also has inherent equitable powers to enjoin actions of state officials that contradict the federal Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *K.P. v. LeBlanc*, 627 F.3d 115, 124 (5th Cir. 2010); *see also Detgen ex rel. Detgen v. Janek*, 752 F.3d 627, 629 (5th Cir. 2014) (recognizing "implied private cause of action under the Supremacy Clause").

16. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) because this action challenges a Louisiana law that applies to and purports to regulate the sale of AstraZeneca's products in this District. AstraZeneca makes its drugs available and sells its products to multiple 340B covered entities within this District, including several in Lafayette, Louisiana, and these entities maintain multiple contract pharmacy arrangements. *See* HRSA, Covered Entity Search Criteria, https://340bopais.hrsa.gov/CoveredEntitySearch/000077285. The challenged law (if not invalidated) would apply to conduct and property in this District, including AstraZeneca's, and is highly likely to be enforced in this District.

17. Venue is also proper in this Court under 28 U.S.C. § 1391(b)(1) because Defendant maintains offices in this District, including in Lafayette, through which Defendant would enforce the law challenged in this action.

PARTIES TO THE ACTION

18. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware. AstraZeneca is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines. AstraZeneca participates in the 340B program.

19. Defendant Jeff Landry is the Attorney General of the State of Louisiana. His official address is in Baton Rouge, and he maintains offices within this District in Alexandria, Lafayette, Monroe, and Shreveport. He has ultimate responsibility for enforcing the laws of the State of Louisiana, including Act 358 and the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. § 51:1401 *et seq*. He is sued in his official capacity.

FACTUAL ALLEGATIONS

The Federal 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations

20. Section 340B of the federal Public Health Service Act is a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

21. As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. 42 U.S.C. § 256b(a)(1). In that agreement, the manufacturer must

"offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III). The 340B statute also regulates covered entities, which may not obtain 340B pricing on units of drugs for which a manufacturer pays a Medicaid rebate (known as "duplicate discounts"), nor resell or otherwise transfer such drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(A), (B).

22. Congress enacted Section 340B "to enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

23. Congress has added to the list of 340B covered entities over time, and today there are fifteen delineated categories of covered entities. 42 U.S.C. § 256b(a)(4)(A)-(*O*).

24. Notably, Congress has *never* included contract pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259, at 1-2 (1992) (requiring manufacturer to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). But that provision was not enacted.

25. The 340B program has its own federal enforcement provisions and administrative dispute-resolution process. Congress required the Secretary of HHS to establish an adjudicatory body to resolve disputes among the participants in the 340B program, including "claims by covered entities that they have been overcharged for drugs purchased under this section [340B], and claims by manufacturers … of violations" by covered entities. 42 U.S.C. § 256b(d)(3)(A). Under that statutory mandate, HRSA has established "requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process" in a 2020 rule. 85 Fed. Reg. 80,632 (Dec. 14, 2020) (the ADR Rule). The ADR Rule authorizes panels of federal officers to resolve claims for "money damages," as well as other unspecified "equitable relief" sought by claimants. 42 C.F.R. § 10.21. And the ADR Rule empowers ADR panels to address a range of factual and legal disputes, including "those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales." 85 Fed. Reg. at 80,636.

26. HRSA continues to refine the 340B ADR process. In November 2022, it issued a Notice of Proposed Rulemaking that includes a number of revisions to the program, including making the adjudication process less formal, altering the composition of panels, and narrowing the panels' jurisdiction. *See generally* 87 Fed. Reg. 73,516 (Nov. 30, 2022). The current ADR process remain in place until the effective date of the final rule.

Contract Pharmacy Use Leads to Abuse and Profiteering

27. Section 340B does not require manufacturers to deliver 340B-discounted drugs to contract pharmacies—or indeed, to *any* entity not specifically enumerated in the statute. In the decades since the enactment of the program, however, HRSA has issued two non-binding "guidance" documents purporting to authorize covered entities to enter into agreements with contract pharmacies to dispense outpatient drugs under Section 340B.

28. In 1996, HRSA issued guidance providing that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now enter into an agreement with a *single* outside pharmacy of its choice to provide such services for 340B drugs. 61 Fed. Reg. 43,555 (Aug. 23, 1996) (1996 Guidance).

29. Then, in 2010, HRSA released new guidance stating that covered entities must now be permitted to "use multiple pharmacy arrangements"—that is, an *unlimited* number of contract pharmacies, without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." 75 Fed. Reg. 10,273 (2010 Guidance). The 2010 Guidance thus purported to authorize a covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States.

30. The 2010 Guidance triggered a massive surge in the number of contract pharmacies receiving and distributing 340B drugs. In 2018, the Government Accountability Office reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 by 2017. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2, 10 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/700/692697.pdf. These numbers have continued to escalate. Today, more than 33,000 different pharmacies participate in the 340B program, with more than 194,000 individual contracts. Adam J. Fein, Drug Channels Inst., *Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market* (Jul. 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html. The vast majority of these contract pharmacies (75% as of 2018) are national, for-profit retail pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and

Kroger—accounted for a combined 60% of all 340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

31. Make no mistake: The boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B discounted drugs. The determination whether a medicine dispensed at a contract pharmacy is eligible for the 340B discount is not made until *after* the medicine is dispensed to the patient and paid for at a non-discounted, commercial price by the patient and his or her health plan. In practice, pharmacies generally buy their inventory of drugs from wholesalers in commercial transactions. Pharmacies then dispense those medicines to any patient with a valid prescription. Those patients could have been treated at a 340B entity or a non-340B entity. Either way, the pharmacy dispenses product from its inventory to the patient consistent with the patient's insurance. Later, for medications determined to be dispensed to a patient of the 340B entity, the wholesaler processes a chargeback reflecting the difference between the pharmacy acquisition price and the 340B price. Decl. of Krista M. Pedley ¶¶ 5-9, *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2. This means that a 340B discount is applied for the contract pharmacy sale even though it has *also* benefitted from the full insurance reimbursement. The pharmacy may well share some of its windfall with the covered entity or the covered entity's vendor, but the patient has still paid the full out-of-pocket amount designated under his or her insurance policy.

32. As Senator Chuck Grassley put it in a letter to HRSA, for-profit pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Adm'r, HRSA (Mar. 27, 2013), https://www.grassley.senate.gov/download/2013-03-27-ceg-to-

hrsa-340b-oversight-3. The result is "hundreds of millions" of dollars siphoned off from the 340B program in the form of contract-pharmacy profits. *See* Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge* (Sept. 9, 2020).

33. Although some of the money generated through contract pharmacy sales is passed on to covered entities, most of these profits are *not* going to federally qualified health centers or other federal grantees that provide services to underserved populations (such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance programs). Instead, they are being captured by 340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. Aaron Vandervelde et al., Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 7 (Oct. 2020), https://bit.ly/3owtUwa.

34. Nor are these huge profits being passed on to patients. For example, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. As for the remaining 55%, the GAO noted that entities using contract pharmacies may provide discounts to patients only in limited cases. *Id*. Likewise, the HHS Office of Inspector General found in 2014 that many contract pharmacies do not offer 340B discounted prices to uninsured patients at all. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 4, 2014) (2014 OIG Report), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.* By contrast, the GAO noted that 17 of 23 of the surveyed covered entities that used *in-house* pharmacies reported offering discounts to their patients. 2018 GAO Report at 30 n.46.

35. In short, the widespread proliferation of contract pharmacy arrangements since 2010 has transformed the 340B program from one intended to assist vulnerable patients into a multi-billion-dollar arbitrage scheme that benefits national for-profit pharmacy chains and other for-profit intermediaries.

36. At the same time, the explosive growth of contract pharmacy arrangements also has facilitated increased diversion and duplicate discounts. A 2011 report from the Government Accountability Office warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28, (Sept. 23, 2011), https://www.gao.gov/assets/330/323702.pdf. The report further found that "HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

37. These structural problems have only intensified over time, as the use of multiple contract pharmacies has become rampant. The 2014 OIG report determined that self-policing by covered entities has been insufficient to stop these abuses, since "most covered entities . . . do not conduct all of the oversight activities recommended by HRSA." 2014 OIG Report at 2. The 2018 GAO Report similarly criticized the continuing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies." 2018 GAO Report at 45.

38. Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved drugs distributed at contract pharmacies." *Id.*

at 44. And based on information from HRSA's website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. Indeed, out of 199 audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results.

AstraZeneca's 340B Policy and Resulting Litigation

39. Against this legal and factual backdrop, in August 2020 AstraZeneca announced to covered entities that, effective October 1, 2020, it would revert to the contract pharmacy approach set forth in HRSA's 1996 Guidance.

40. Under this policy, AstraZeneca continues to make its products available at 340B-discounted prices—in unlimited quantities—to all covered entities. For covered entities that do not maintain their own on-site dispensing pharmacy, AstraZeneca delivers discounted drugs to a single contract pharmacy site for each covered entity. But AstraZeneca no longer delivers 340B drugs to an unlimited number of contract pharmacies.

41. AstraZeneca's policy is consistent with the letter and intent of the 340B program—limiting the potential for abuse, while still enabling all covered entities and their patients to continue to access AstraZeneca's medicines at 340B prices. Under AstraZeneca's policy, several thousand covered entities that lack an on-site pharmacy have registered a contract pharmacy to which AstraZeneca continues to deliver 340B-discounted drugs, including approximately 50 covered entities in Louisiana. AstraZeneca is committed to working with all covered entities to ensure that every patient can obtain needed medicines at prices they can afford.

42. In response to AstraZeneca's new contract pharmacy policy and other manufacturers' adoption of similar policies, HHS and HRSA issued an Advisory Opinion on

December 30, 2020, asserting that the 340B statute requires manufacturers to deliver 340B-discounted drugs for unlimited contract pharmacy sales.

43. In early 2021, AstraZeneca filed suit in the U.S. District of Delaware Federal Court against HHS and HRSA, challenging the Advisory Opinion. On June 16, 2021, the Delaware Federal Court issued a detailed opinion finding the Advisory Opinion unlawful. *AstraZeneca Pharms. LP v. Becerra* (*AstraZeneca I*), 543 F. Supp. 3d 47 (D. Del. 2021). The court concluded that Section 340B "says nothing about the permissible role (if any) of contract pharmacies," and that, in light of this "total omission," the Advisory Opinion's attempt to impose an obligation on AstraZeneca to deliver discounted drugs to unlimited contract pharmacies was "legally flawed." *Id.* at 59. The agency withdrew the Advisory Opinion following the Delaware Federal Court's ruling.

44. In a second ruling, the Delaware Federal Court addressed AstraZeneca's challenge to a "violation letter" issued by HRSA, which adopted the same position as the Advisory Opinion. The Delaware Federal Court again rejected the agency's view that the 340B statute obligates drug manufacturers to deliver 340B drugs for contract pharmacy sales. *AstraZeneca Pharms. LP v. Becerra* (*AstraZeneca II*), No. 1:21-cv-27, 2022 WL 484587 (D. Del. Feb. 16, 2022). The court reiterated "key points" from its prior opinion, including that Congress "did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." *Id.* at *5-*6.

45. The government appealed, but, on January 30, 2023, the U.S. Court of Appeals for the Third Circuit affirmed the Delaware Federal Court's rulings. In a consolidated opinion addressing AstraZeneca's case and appeals in parallel actions by other manufacturers, the Third Circuit held that the Advisory Opinion and violation letter are "unlawful," and it "enjoin[ed] HHS

from enforcing against" AstraZeneca HHS's "reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 706 (3d Cir. 2023). The court of appeals also held that AstraZeneca's "restrictions on delivery to contract pharmacies do not violate Section 340B." *Id.*

46. The government neither sought en banc review of the Third Circuit's decision nor filed a petition for certiorari in the U.S. Supreme Court.

47. On May 5, 2023, the Delaware Federal Court issued a final judgment in AstraZeneca's case, to which the government stipulated. The court's order provides that it is:

a. "DECLARED that Advisory Opinion 20-06 and the Violation Letter from the Health Resources and Services Administration to Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca), dated May 17, 2021 (Violation Letter), are unlawful;

b. DECLARED that AstraZeneca's policy limiting the use of contract pharmacies under Section 340B of the Public Health Service Act (Section 340B), 42 U.S.C. § 256b—namely, that covered entities may use an in-house pharmacy and, if they do not have an in-house pharmacy, they may use one contract pharmacy—does not violate Section 340B;

c. ORDERED that the Violation Letter is VACATED as contrary to law pursuant to 5 U.S.C. § 706;

d. ORDERED that Defendants, including their officers, agents, and employees, are ENJOINED from enforcing against AstraZeneca the agency's reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies."

Final Judgment at 1, *AstraZeneca*, No. 1:21-cv-27 (D. Del. May 5, 2023), ECF No. 123 (Exhibit 1).

48. As a result of the Third Circuit's ruling and the Delaware Federal Court's injunction, AstraZeneca is entitled to proceed with its lawful contract pharmacy policy.[*]

Louisiana Enacts 340B Legislation Mandating Unlimited Sales to Contract Pharmacies

49. On June 12, 2023, one month after the final judgment was issued in AstraZeneca's action in Delaware, Governor John Bel Edwards signed the "Defending Affordable Prescription Drug Costs Act." 2023 La. Sess. Law Serv. Act 358 (adding Sections 2881-2886 to Title 40 of the Louisiana Revised Statutes).

50. Act 358 expressly provides that its regulatory object is the federal 340B program. Section 2882 defines the terms "340B drug" and "340B entity" by reference to 42 U.S.C. § 256b, the 340B statute. *See* La. Rev. Stat. § 40:2882(1), (2) (defining terms).

51. Act 358 then imposes two sets of substantive prohibitions. *First*, Section 2883 generally bars health insurance issuers, pharmacy benefit managers, and other third-party payors from reducing reimbursements and imposing certain conditions and requirements on 340B entities and 340B drugs based on their 340B status. La. Rev. Stat. § 40:2883.

52. *Second*, Section 2884, titled "Prohibition of certain discriminatory actions by a manufacturer or distributor related to 340B entities," mandates:

a. "A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or

[*] Shortly after the ADR Rule went into effect in January 2021, the National Association of Community Health Centers, a trade group that represents covered entities, filed an ADR petition against AstraZeneca, alleging that AstraZeneca was in violation of the 340B statute by failing to deliver 340B-priced drugs to contract pharmacies. On August 10, 2022, the ADR panel dismissed the claim on the ground that the federal litigation "precludes our consideration of this dispute." Order Granting Mots. to Dismiss at 8, *NACHC v. Sanofi-Aventis U.S. LLC & AstraZeneca PLC*, No. 210112-2 (Exhibit 2).

delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.

b. A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity."

Id. § 40:2884(A)-(B).

53. Section 2885 provides that commission of any act prohibited by the new chapter is a violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Stat Ann. 51:1401 *et seq*. *Id.* § 40:2885. The commission of a prohibited act "subjects the violator to any and all actions, including investigative demands, remedies, and penalties provided for in the Unfair Trade Practices and Consumer Protection Law, except there shall be no right to bring a private action pursuant to R.S. 51:1409. A violation occurs each time a prohibited act is committed." *Id.*

54. The Unfair Trade Practices and Consumer Protection Law authorizes the Attorney General, and district attorneys under his supervision, to seek "a civil penalty against any person found by the court to have engaged in any method, act, or practice in Louisiana declared to be unlawful" by the statute. La. Rev. Stat. §§ 51:1407(B), 51:1417. The Attorney General and district attorneys may also bring actions for injunctive relief to enjoin use of "any method, act, or practice declared by R.S. 51:1405 to be unlawful." *Id.* § 51:1407(A). The statute also authorizes courts to issue additional orders or render judgments against any party to compensate any aggrieved person for any property unlawfully acquired. *Id.* § 51:1408. Such orders may include restitution, as well revocation of licenses or other authority to conduct business, appointment of a receiver, dissolution

of Louisiana corporate entities, and suspension or termination of foreign corporate entities' right to do business in Louisiana. *Id.*

55. Finally, Act 358 includes Section 2886, entitled "Federal preemption," which includes three purported limitations on the scope of the statute:

a. "Nothing in this Chapter is to be construed or applied to be less restrictive than federal law for a person or entity regulated by this Chapter." *Id.* § 40:2886(A).

b. "Nothing in this Chapter is to be construed or applied to be in conflict with any of the following: (1) Applicable federal law and related regulations. (2) Other laws of this state if the state law is compatible with applicable federal law." *Id.* § 40:2886(B).

c. "Limited distribution of a drug required under 21 U.S.C. 355-1 is not to be construed as a violation of this Chapter." *Id.* § 40:2886(C).

56. The operation and apparent intent of Act 358 is to compel pharmaceutical manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies, notwithstanding the Third Circuit's prior ruling holding that federal law imposes no such requirement.

LEGAL ALLEGATIONS

Act 358 Violates the Supremacy Clause

57. The Supremacy Clause of the U.S. Constitution provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof," are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "The doctrine of federal preemption that arises out of the Supremacy Clause requires that 'any state law, however clearly within a State's acknowledged power, which

interferes with or is contrary to federal law, must yield.'" *Aldridge v. Miss. Dep't of Corr.*, 990 F.3d 868, 874 (5th Cir. 2021) (quoting *Felder v. Casey*, 487 U.S. 131, 138 (1988)).

58. Act 358's mandates for drug manufacturers and its associated enforcement mechanisms are preempted by the 340B statute under the Supremacy Clause in three respects.

59. ***First***, Act 358 conflicts directly with Section 340B, 42 U.S.C. § 256b.

60. Conflict preemption occurs when "compliance with both state and federal law is impossible," in which case "state law, however clearly within a State's acknowledged power, . . . must yield." *Aldridge*, 990 F.3d at 874-75 (citation omitted). "[C]onflict preemption does not require 'a specific, formal agency statement identifying conflict in order to conclude that such a conflict in fact exists.'" *Id.* at 875 (quoting *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 884 (2000)).

61. The obligations imposed by Act 358 on manufacturers like AstraZeneca directly conflict with the decision of the U.S. Court of Appeals for the Third Circuit that AstraZeneca's "restrictions on delivery to contract pharmacies do not violate Section 340B." *Sanofi Aventis U.S. LLC*, 58 F.4th at 706; *see id.* (rejecting HHS's "reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies").

62. Act 358 also conflicts with the permanent injunction entered by the U.S. District Court for the District of Delaware Federal Court. The court enjoined HHS, HRSA, and their officers from "enforcing against AstraZeneca the agency's reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies." Final Judgment at 1, *AstraZeneca*, No. 1:21-cv-27 (D. Del. May 5, 2023), ECF No. 123 (Exhibit 1).

63. The Third Circuit and Delaware Federal Court rulings make unmistakably clear that the 340B statute does *not* obligate manufacturers to deliver discounted drugs to unlimited

contract pharmacies, and that any attempt by federal officials to impose such an obligation would be unlawful.

64. Act 358 adopts the same position that was rejected in the federal litigation and seeks to impose on AstraZeneca the same obligations that were ruled unlawful there: The Louisiana law purports to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies.

65. Under the Supremacy Clause, Louisiana may not compel private entities to comply with Louisiana's preferred interpretation of a federal statute when federal courts have rejected that very interpretation and have enjoined the federal government from applying it to the same entities. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 486 (2013).

66. ***Second***, Act 358 "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (citation omitted).

67. The Supremacy Clause prohibits states from establishing parallel regimes that encroach on the federal government's authority to set and define federal enforcement priorities. *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 349 (2001).

68. Act 358 directly interferes with the robust federal enforcement regime that Congress has enacted for the 340B program, which includes the ADR process, required auditing provisions for manufacturers and covered entities, and the possibility of civil monetary penalties in the event of a manufacturer overcharge or diversion by a covered entity.

69. By inserting Louisiana and its officials into the program that Congress adopted, Act 358 frustrates the accomplishment of Congress's objectives and interferes with Congress's chosen method of oversight.

70. ***Third***, Act 358 is preempted because Congress has created and occupied the entire field of 340B regulation.

71. "[T]he States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Arizona v. United States*, 567 U.S. 387, 399 (2012). "Field preemption exists when (1) 'the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation,' or (2) 'where the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Aldridge*, 990 F.3d at 874 (quoting *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)).

72. The 340B program is a comprehensive scheme that protects a dominant federal interest. Congress created it to assist vulnerable populations and has established appropriate boundaries for the program, including by carefully delineating the categories of eligible covered entities. The entirety of the program—including relevant prices, participants, and enforcement mechanisms—is defined by federal law.

73. In *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), the Supreme Court held that private entities may not bring actions under state contract law to enforce the provisions of manufacturers' 340B pharmaceutical pricing agreements. *Id.* at 113-14. "Congress made HHS administrator of … the 340B Program." *Id.* at 120. Suits by private entities, the Court explained, "would undermine the agency's efforts" to administer the program "harmoniously and on a uniform, nationwide basis." *Id.* "With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.*

74. Those principles apply equally to preclude state legislation purporting to administer and impose new requirements under the 340B program. Manufacturers' obligations under the program are defined by federal law, as interpreted by federal courts, and are enforced by federal officials.

75. Act 358 impermissibly intrudes into this uniquely federal domain. In effect, the law creates a new, sixteenth category of covered entity to which AstraZeneca must deliver unlimited 340B-discounted drugs: contract pharmacies. The statute thus interferes with the careful balance that Congress established in the 340B program, which takes account of both the need to stretch scarce federal resources and the financial and logistical burdens imposed on the manufacturer participants in the program.

Act 358 Violates the Contracts Clause

76. Act 358 also violates the Contracts Clause of the U.S. Constitution. Article I, section 10 of the Constitution provides, "No State shall ... pass any … Law impairing the Obligation of Contracts." Courts have interpreted the Contracts Clause to require a "three-part test to balance the State's obligation not to impair contracts with the State's interest in public welfare." *Lipscomb v. Columbus Mun. Separate Sch. Dist.*, 269 F.3d 494, 504 (5th Cir. 2001). First, the court asks whether the state law "has, in fact, operated as a substantial impairment of a contractual relationship." *Id.* (citation omitted). Second, if the court finds substantial impairment, it "must consider the justification offered by the State for its impairment of the contract." *Id.* Third, "if the State presents a legitimate justification for the impairment," the court must "determine whether the impairment is reasonable and necessary." *Id.* at 505.

77. Act 358 fails at every stage of this test. Act 358 substantially impairs a contractual relationship. As explained above, the 340B program operates through contracts, which are called pharmaceutical pricing agreements (PPAs). PPAs are "uniform agreements that recite the

responsibilities § 340B imposes . . . on drug manufacturers and the Secretary of HHS." *Astra USA*, 563 U.S. at 113. While PPAs are not "transactional, bargained-for contracts," *id.*, they nonetheless announce the parties' rights and obligations like any other contract, and manufacturers like AstraZeneca are entitled to rely on the PPA's terms when developing their business. Among those terms is the requirement that manufacturers offer discounted drugs only to a specifically delineated set of "covered entities." As the Third Circuit recently underscored, neither the 340B statute nor the PPA requires AstraZeneca to deliver discounted drugs to an unlimited number of for-profit contract pharmacies that Congress has not designated as covered entities. *Sanofi Aventis U.S. LLC*, 58 F.4th at 706.

78. Act 358 operates as a substantial impairment of AstraZeneca's PPA with the HHS Secretary. AstraZeneca joined the 340B program with the expectation and understanding that it would be required to provide discounted drugs to only a limited number of covered entities, and it accepted that obligation. Act 358 seeks to unilaterally expand AstraZeneca's obligations under that contract—without AstraZeneca's consent—by requiring AstraZeneca to deliver discounted drugs to an entirely new category of entities: contract pharmacies.

79. Both the Supreme Court and the Fifth Circuit have held that similar expansions of beneficiaries to a contract constitutes substantial impairment under the Contracts Clause. *See Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 245-46 (1978) (Contracts Clause prohibited Minnesota from requiring company to provide additional pension benefits after it had agreed to provide pension benefits under specific contractual conditions); *United Healthcare Ins. Co. v. Davis*, 602 F.3d 618, 630 (5th Cir. 2010) (Contracts Clause prohibited Louisiana from enacting legislation increasing obligations on companies that had agreed to insure state employees under specific conditions).

80. Any justification Louisiana might offer for Act 358 would be insufficient under the Contracts Clause. Louisiana cannot claim that its law is necessary to provide access to 340B drugs to covered entities and their patients, because AstraZeneca's policy already ensures that every covered entity is offered those drugs at a discounted price. Indeed, AstraZeneca's policy goes further, allowing covered entities to designate a single contract pharmacy if it does not have an on-site pharmacy to dispense AstraZeneca's drugs.

81. Louisiana has no legitimate justification for requiring unlimited contract pharmacy arrangements, which will advance the economic interests of for-profit pharmacies at the expense of companies like AstraZeneca, particularly where Congress itself has not required them.

82. Nor can Louisiana justify Act 358 as a cost-reduction mechanism for patients. Studies show that most 340B discounts to contract pharmacies are *not* passed on to patients, who must pay full price for their drugs. *See* ¶ 34, *supra*.

83. Finally, even if the State could articulate a legitimate justification for Act 358's impairment of AstraZeneca's PPA, that justification would not be reasonable and necessary to achieve the State's goals.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Act 358 is Preempted by Federal Law Supremacy Clause, U.S. Const. art. VI, cl. 2)

84. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

85. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law," *Aldridge*, 990 F.3d at 874 (citation

omitted). The mandates imposed on drug manufacturers by Act 358, and its associated enforcement mechanisms, are preempted by the 340B statute under the Supremacy Clause.

86. Act 358 conflicts directly with Section 340B. The obligation imposed by Act 358 on manufacturers—to deliver 340B-discounted drugs to unlimited contract pharmacies—directly conflicts with federal court rulings upholding AstraZeneca's contract pharmacy policy and enjoining HHS and HRSA from enforcing against AstraZeneca the same reading of the 340B statute that Act 358 now mandates. Louisiana may not compel manufacturers to comply with a statutory interpretation that federal courts have already declared unlawful.

87. Act 358 also creates an obstacle to the accomplishment and execution of Congress's objectives for the 340B statute. Congress has enacted a comprehensive regime for enforcement and management of the 340B program, which includes the ADR process, audits, and civil monetary penalties. Act 358's attempt to insert into Congress's program a layer of enforcement by state officials under Louisiana law frustrates Congress's purposes and interferes with the carefully specified federal regime it created.

88. Finally, Congress created and occupied the entire field of regulation under Section 340B. The program is a comprehensive scheme that balances the federal interests, including assisting vulnerable populations and preserving program integrity. Act 358 intrudes into this exclusive federal domain by effectively adding a new category of covered entity—contract pharmacies—to the exclusive statutory list. In constructing the 340B program, Congress left no room for supplementary state regulation.

89. For these reasons, Act 358's provisions requiring manufacturers to distribute 340B drugs to unlimited contract pharmacies, and empowering Defendant Landry and district attorneys

to pursue purported violations of the statute, are preempted by federal law under the Supremacy Clause.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – Act 358 Violates the Contracts Clause Contracts Clause, U.S. Const. art. I, § 10, cl. 1)

90. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

91. Under the Contracts Clause, U.S. Const. art. I, § 10, cl. 1, "[n]o State shall ... pass any … Law impairing the Obligation of Contracts." The Contracts Clause imposes an obligation on States "not to impair contracts," and it prohibits States from enacting legislation that "operate[s] as a substantial impairment of a contractual relationship." *Lipscomb v. Columbus Mun. Separate Sch. Dist.*, 269 F.3d 494, 504 (5th Cir. 2001).

92. Act 358 violates the Contracts Clause.

93. Act 358 substantially impairs AstraZeneca's PPA with the HHS Secretary by requiring delivery of 340B drugs to contract pharmacies, thus purporting to substantially expand AstraZeneca's obligations under the agreement beyond what the agreement itself provides.

94. Louisiana has no valid justification for impairing AstraZeneca's PPA. AstraZeneca's policy ensures that every covered entity is offered 340B drugs at statutorily required prices. The policy also allows covered entities without an on-site pharmacy to utilize a single contract pharmacy, which is more than the statute requires. Compelling AstraZeneca to provide 340B-discounted drugs to unlimited contract pharmacies would advance the economic interests of for-profit pharmacies at AstraZeneca's expense, with little to no cost benefit to 340B patients.

95. Even if Louisiana could identify a legitimate justification for impairing AstraZeneca's PPA, it would not be reasonable and necessary to achieve the State's goals.

96. Act 358 is unconstitutional under the Contracts Clause to the extent it requires AstraZeneca to deliver discounted drugs to contract pharmacies that do not qualify as covered entities, and which therefore are not included within the anticipated or actual scope of the PPA that AstraZeneca signed with the HHS Secretary.

PRAYER FOR RELIEF

NOW, THEREFORE, AstraZeneca requests a judgment in its favor against Defendant as follows:

A. Declare that Act 358 is preempted by federal law and is therefore null, void, and unenforceable;

B. Declare that Act 358 is unconstitutional as applied to AstraZeneca under the Contracts Clause of the U.S. Constitution;

C. Declare that AstraZeneca is not required to offer 340B discounts for unlimited contract pharmacy sales under Louisiana law;

D. Issue preliminary and permanent injunctive relief preventing Defendant from implementing or enforcing Act 358 against AstraZeneca or any of its affiliates, officers, agents, or contractors;

E. Issue preliminary and permanent injunctive relief preventing Defendant from seeking civil penalties, equitable relief, or any other remedy based on any alleged violation of Act 358 by AstraZeneca or any of its affiliates, officers, agents, or contractors;

F. Award AstraZeneca reasonable attorneys' fees and costs, as appropriate; and

G. Grant such other and further relief as the Court may deem appropriate.

Dated: August 4, 2023

Respectfully submitted,

ADAMS AND REESE LLP

s/ Diana Cole Surprenant

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** Applications to be admitted pro hac vice forthcoming*

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